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| APPLICATION NO.            | FILING DATE                    | FIRST NAMED INVENTOR                  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|--------------------------------|---------------------------------------|---------------------|------------------|
| 10/599,020                 | 09/18/2006                     | Frederic Ben                          | 58767.000017        | 3183             |
| 21967<br>HUNTON & W        | 7590 07/08/201<br>YILLIAMS LLP | 1                                     | EXAM                | IINER            |
| INTELLECTUA                | AL PROPERTY DEPA               | PROPERTY DEPARTMENT LISTVOYB, GREGORY |                     |                  |
| 1900 K STREE<br>SUITE 1200 | 1, IN. W.                      |                                       | ART UNIT            | PAPER NUMBER     |
| WASHINGTO                  | N, DC 20006-1109               |                                       | 1765                |                  |
|                            |                                |                                       |                     |                  |
|                            |                                |                                       | MAIL DATE           | DELIVERY MODE    |
|                            |                                |                                       | 07/08/2011          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.  | Applicant(s)   |           |
|--|--|--|-----------|
|  | 10/599,020   | BEN ET AL.   |           |
| Office Action Summary  | Examiner   | Art Unit   |           |
|  | GREGORY LISTVOYB   | 1765   |           |
| The MAILING DATE of this communication Period for Reply  | appears on the cover sheet wi  | th the correspondence addre  | ess       |
| A SHORTENED STATUTORY PERIOD FOR REWHICHEVER IS LONGER, FROM THE MAILING  Extensions of time may be available under the provisions of 37 CFF after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory perions to reply within the set or extended period for reply will, by stany reply received by the Office later than three months after the mearned patent term adjustment. See 37 CFR 1.704(b). | COMMUNION DEPTH OF THIS COMMUNION AT 1.136(a). In no event, however, may a reprise of the community of the c | CATION.  eply be timely filed  THS from the mailing date of this command the comment of the comm |           |
| Status   |  |  |           |
| Responsive to communication(s) filed on 0.  2a) This action is <b>FINAL</b> . 2b) ☑ 1  3) Since this application is in condition for allo closed in accordance with the practice under   | This action is non-final.<br>wance except for formal matt  | ·  | nerits is |
| Disposition of Claims  |  |  |           |
| 4) ☑ Claim(s) 16.18-27 and 34 is/are pending in 4a) Of the above claim(s) is/are withe 5) ☐ Claim(s) is/are allowed. 6) ☑ Claim(s) 16.18-27 and 34 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction an  | drawn from consideration.  |  |           |
| Application Papers   |  |  |           |
| 9) The specification is objected to by the Exam 10) The drawing(s) filed on is/are: a) a Applicant may not request that any objection to Replacement drawing sheet(s) including the cor 11) The oath or declaration is objected to by the  | accepted or b) objected to the drawing(s) be held in abeyar rection is required if the drawing   | ce. See 37 CFR 1.85(a). (s) is objected to. See 37 CFR   | , ,       |
| Priority under 35 U.S.C. § 119   |  |  |           |
| 12) Acknowledgment is made of a claim for fore a) All b) Some * c) None of:  1. Certified copies of the priority docum 2. Certified copies of the priority docum 3. Copies of the certified copies of the papplication from the International But * See the attached detailed Office action for a  | nents have been received.<br>nents have been received in A<br>priority documents have been<br>reau (PCT Rule 17.2(a)).   | pplication No received in this National St   | age       |
| Attachment(s)  1) Notice of References Cited (PTO 892)   | A) 🔲 Interview S   | Summary (PTO-413)  |           |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO/SB/08)</li> <li>Paper No(s)/Mail Date</li> </ol>   | Paper No(s   | Summary (PTO-413)<br>s)/Mail Date<br>nformal Patent Application<br>  |           |

## **DETAILED ACTION**

Examiner reconsiders his opinion regarding limitations of amended claim 1 (formerly objected claim 33). As a result, this Office Action is NON-FINAL one

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New limitation of claim 16 "wherein the quantity of monomer relative to the quantity of (co)oligomerization additive ranges from 2 to 30 molar equivalents and the conversion of monomer is greater than 95%" is indefinite, because the claim above claims a catalytic system. Note that a monomer is not a part of a catalytic system. In addition, the monomer is not defined.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16, 18-27 and 34 rejected under 35 U.S.C. 103(a) as being unpatentable over Gruber et al (US 6355772) in view of Bowman (US 3047524) as evidences by Nevin et al (US 4273920). ) (all cited in the previous Office Action)

Gruber teaches a catalytic system, which contains a strongly acidic ion-exchange polymeric catalyst Amberlist 36 (see Example 8, Column 20, line 55, meeting the relevant limitations of claims 16 and 19-21).

In addition, Gruber teaches an alcohol as a part of reaction mixture (see Column 15, line 5), which used for molecular weight control, meeting the relevant limitations of claims 22-26.

In reference to new claim 34, Gruber discloses degree of polymerization of less 5than 30(see Example 8).

Gruber does not teach both components in one catalytic system.

The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945), 325 U.S. at 335, 65 USPQ at 301, see also also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) and MPEP 2144.07.

Therefore, it would have been obvious to a person of ordinary skills in the art to use Amberlist 36 and alcohol together in one catalytic system. The above compounds fulfill different functions of catalyzing polymerization and regulating its molecular weight.

Gruber does not teach the nature and amount of alcohol used.

Bowman teaches a polymerization of glycolic acid, which is analogous to polymerization of lactic acid disclosed by Gruber.

Bowman teaches an addition of 1-5 mol percent (see Column 2, line 10) of a monohydric aliphatic alcohol, such as methanol, ethanol or hexanol (see Column 1, line 40) or, in general, aliphatic alcohol containing 1-6 carbon atoms (see Column 1, line 40) in order to produce a polymer with desired properties.

Regarding the limitation claiming "the quantity of the one or more lactide and/or glycolide monomer(s), relative to the quantity of (co)oligomerization additive ranges from 2 to 30 molar equivalents", Gruber teaches that the amount of molecular weight control agent should be sufficient to control a molecular weight within the range of 10000 to 300000 (see Column 15, line 10).

As evidences by Nevin the process for synthesis of lactic-glycolic copolymer in melt and solution at the presence of acidic ion-exchange resin produces a polymer with Molecular weight within the range of 6000-35000. (see Abstract).

It has long been an axiom of United States patent law that it is not inventive to discover the optimum or workable ranges of result-effective variables by routine experimentation. In re Peterson, 315 F.3d 1325, 1330 (Fed. Cir. 2003) ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Boesch, 617 F.2d 272,276 (CCPA 1980) ("[D]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art."); In re Aller, 220 F.2d 454,456 (CCPA 1955) ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."). "Only if the 'results of optimizing a variable' are 'unexpectedly good' can a patent be obtained for the claimed critical range." In re Geisler, 116 F.3d 1465, 1470 (Fed. Cir. 1997)(quoting In re Antonie, 559 F.2d 618, 620 (CCPA 1977)).

Therefore, it would have been obvious to a person of ordinary skills in the art to add 1-5 mol percent of aliphatic alcohol containing 1-6 carbon atoms to Gruber's system at the suitable amount in order to obtain a polymer with desired properties (i.e. required molecular weight).

Regarding new limitation of amended claim 1, Gruber does not teach a monomer conversion of greater than 95%.

However, since Gruber's catalytic system, modified with Bowman is identical to Applicant's one, their physical and chemical properties, including the ability to catalyze a chemical reaction are equal.

## Response to Arguments

Applicant's arguments filed 6/02/2011 have been fully considered but they are not persuasive.

Examiner reconsiders his opinion regarding limitations of amended claim 1 (formerly objected claim 33) (see Rejection above).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY LISTVOYB whose telephone number is (571)272-6105. The examiner can normally be reached on 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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GL /GREGORY LISTVOYB/ Examiner, Art Unit 1765